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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,586	BLACKSHEAR ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-61,71 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-61,71 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Prosecution is Reopened

1. In view of the pre-appeal brief conference decision of 28 February 2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

2. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

3. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Specification

4. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

> Throughout this application, various publications, patents, and/or patent applications are referenced in order to more fully describe the state of the art to which this invention pertains. The disclosures of these publications, patents, and/or patent applications are herein incorporated by reference in their entireties to the same extent as if each independent publication, patent, and/or patent application was specifically and individually indicated to be incorporated by reference.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

5. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

6. As set forth In *Ex parte* Raible, 8 USPQ2d 1707, (BPAI, 1998)

> The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree
>
> * * *
>
> We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. *In re de Seversky* , 474 F.2d 671, 177 USPQ 144 , (CCPA 1973).

7. Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph. Applicant is urged to consider removing language, which states that the various documents have been incorporated by reference.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 53-61 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not

'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

10. Page 9-12 of the specification provides a definition of "TTP-like polypeptide." Starting at page 9, last paragraph, applicant defines "TTP-like polypeptide" thusly:

> By "TTP-like polypeptide" or "TZF polypeptide" is meant a polypeptide that displays TTP-like activity, i.e., can bind to a class II ARE and can stimulate deadenylation and/or degradation of an mRNA molecule containing a class II ARE. A TTP-like polypeptide can be a polypeptide consisting of only the 64 amino acid tandem zinc finger (TZF) domain having the TZF amino acid consensus sequence (representatives of which are shown in Fig. 5B), or a TZF polypeptide can be a larger polypeptide comprising the TZF domain (for example, a naturally occurring polypeptide such as ERF1 or ERF2), or the TZF polypeptide may contain the TZF domain plus additional amino acid sequences, as long as the TTP-like polypeptide can carry out its TTP-like activities of binding a class II ARE and stimulating mRNA deadenylation and/or degradation. A polypeptide having the amino acid sequence of full-length human TTP or full-length rodent TTP is excluded from this definition.

11. Various non-limiting examples are provided. Page 12 identifies some "naturally occurring TTP-like (TZF) polypeptides- ERF1/CMG1, ERF2/TIS11D/XC3H-3-2, XC3H-3.1, XC3H-1, CTH1 (carp), CTH1 (zebrafish), and XC3-H-4.

12. A review of the disclosure finds the following examples:

- Example 1, pages 33-50, "TTP is a Regulator of GM-CSF mRNA Deadenylation and Stability;"
- Example 2, pages 50-60, "Inhibitor of Macrophage TNFα Production by TTP;"
- Example 3, pages 61-87, "Evidence that TTP Binds to AU-Rich Elements and Promotes the Deadenylation and Destabilization of TNFα mRNA;" and
- Example 4, pages 87-106, "The tandem zinc finger domain from TTP and TTP-related proteins binds to AU-rich elements and destabilizes mRNA."

13. In contrast, claim 53, the sole independent claim, is directed to "a method of identifying a compound that modulates the binding of tristetraprolin (TTP) or a TTP-like polypeptide to an AU-rich element (ARE).

14. As is plainly evident, none of the examples is drawn to the claimed method. A review of the disclosure fails to locate the requisite full, clear, concise and exact disclosure that fully enables a reproducible method encompassed by the claims currently before the office. More specifically, the disclosure is essentially silent as to appropriate combinations of starting materials and reaction conditions for even one embodiment of the claimed invention, whether or not the claims are limited to TTP-polypeptide or to a TTP-like polypeptide.

15. Page 31, last paragraph, states in part: "[C]ompounds that modulate the activity of TTP and TTP-like polypeptides may be identified from large libraries of natural products or synthetic (or semi-synthetic) extracts or chemical libraries according to methods known in the art. Those skilled in the filed of drug discovery and development will understand that the precise source of test extracts or compounds is not critical to the screening procedure(s) of the invention. Accordingly, virtually any number of chemical extracts or compounds can be screened using the

exemplary methods described herein." As can be seen above, however, none of the examples provided are drawn to the claimed invention.

16. In addition to the general absence of an enabling disclosure for TTP polypeptides, the specification is also silent as to the methods of screening when one uses a TTP-like polypeptide. Indeed, the TTP-like polypeptide may be artificial in origin. While the specification does identify some "naturally occurring" TTP-like polypeptides, the specification is silent as to how even these polypeptides are to be tested.

17. While applicant has sought to incorporate numerous documents, said documents have been improperly incorporated by reference and as such cannot be relied upon for satisfaction of the written description, enablement or best mode requirements of 35 USC 112, first paragraph.

18. Assuming *arguendo*, that the documents could be relied upon, a point that the Office does not concede, the specification still does not set forth in sufficient detail, e.g., by way of exemplification or any other form of description, how the claimed invention is to be practiced.

19. It is noted that the method of claim 54 is to not only identify a compound that "modulates the binding of TTP or a TTP-like polypeptide to an ARE" (claim 53), but it is to also identify "a compound that stimulates an activity of a TTP or a TTP-like polypeptide." The method, however, does not recite any method steps whereby a correlation in activity is measured. As presently worded, the addition of hot water, which could denature the TTP and/or TTP-like polypeptide, would certainly "modulate the binding of TTP or a TTP-like polypeptide to an ARE," yet reason dictates that it would not increase activity. However, as presently claimed, the method does not recite any method steeps that would allow the skilled artisan to differentiate between compounds that modulate binding yet do not increase activity.

20. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.
For the above reasons, and in the absence of convincing evidence to the contrary, claims 53-61 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim Rejections - 35 USC § 101

21. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

22. Claims 53-61, 71, and 72 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility.

23. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines. In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manso*n, 148 USPQ 689 (US Sup Ct 1966):

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from

> an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> * * *
>
> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. (Emphasis added)

24. At page 18, line 21, bridging to page 19, line 3, applicant asserts "TTP deficiency has similar effect on the stability of another mRNA containing a class II ARE, i.e., the mRNA encoding GM-CSF... The present studies allow for the development of new therapeutic approaches for stimulating GM-CSF production, for example, in a patient or subject, by increasing the stability of its mRNA." Page 19, lines 18-21, state "[t]he patient can be human or non-human primate, or any animal that experiences granulocytopenia (e.g., a cat, a dog, a horse, a bird, or a rodent) as part of a pathological condition or exposure to a granulocyte-depleting amount of a toxic substance (e.g., a chemotherapeutic agent). Additionally, populations of cells in vitro can be enriched for granulocytes according to the present method. These cells may be from cell culture of they may be primary cells ex vivo. These populations of cells can be used as research tools to study GM-CSF or they can be returned to the subject."

25. In order for the claimed method to have utility, the method must give rise to a product that satisfies the utility requirements of 35 USC 101, or has been shown to give rise to a product

or method that in turn has utility in a readily available form. In the present case, the specification does not teach where any compound has been identified by the claimed method, much less that the product so identified has in fact been found to satisfy the utility requirements, either directly or indirectly. Therefore, and in the absence of convincing evidence to the contrary, claims 53-61, 71, and 72 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well-established utility.

26. Claims 53-61, 71, and 72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

27. The rejection of claims under 35 USC 112, first paragraph, as failing to comply with the written description requirement has been withdrawn.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BLS
02 May 2006